PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61K 9/68, A23G 3/30

A1

(11) International Publication Number: **WO 00/62762**

(43) International Publication Date: 26 October 2000 (26.10.00)

(21) International Application Number: PCT/US00/07410

(22) International Filing Date: 21 March 2000 (21.03.00)

(30) Priority Data:
60/129,488 15 April 1999 (15.04.99) US

(71) Applicant *(for all designated States except US)*: WM. WRIGLEY JR. COMPANY [US/US]; Wrigley Building, 410 North Michigan Avenue, Chicago, IL 60611–4287 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MAZUREK, Pam, M. [US/US]; 14040 Michael Drive, Orland Park, IL 60462 (US). REED, Mike [US/US]; 5341 Lincoln, Merrillville, IN 46410 (US). BRODERICK, Kevin [US/US]; 1527 Wenonah, Berwyn, IL 60402 (US).

(74) Agent: BARRETT, Robert, M.; Hill & Simpson, 233 South Wacker Drive, Sears Tower – 85th Floor, Chicago, IL 60606 (US).

(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: CHEWING GUM WITH DENTAL BENEFITS INCLUDING CALCIUM IN A FOOD GRADE ACID

(57) Abstract

Methods and chewing gums for the remineralization of tooth enamel are provided. To this end a sugar free chewing gum comprising an insoluble portion, a water soluble portion, a flavor, calcium carbonate, and a food grade acid is provided as well as methods of using same.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

SPECIFICATION

TITLE

"CHEWING GUM WITH DENTAL BENEFITS INCLUDING CALCIUM IN A FOOD GRADE ACID"

BACKGROUND OF THE INVENTION

The present invention relates generally to chewing gums. More specifically, the present invention relates to chewing gums that can provide dental benefits.

Except for the common cold, dental caries (tooth decay) is the most prevalent human disorder. See, *The Merck Manual*, Sixteenth Edition, p. 2480. Even though, many steps have been taken to reduce dental caries and tooth decay, such as fluoridation and improved dental care, tooth decay continues to be a significant problem. This is especially true in the adult population; 80% of the tooth decay occurs in 20% of the population. See Featherstone, *An Updated Understanding of the Mechanism of Dental Decay and its Prevention,* Nutrition Quarterly, Vol. 14, No. 1, 1990, pp. 5-11.

To protect a normal tooth, a thin layer of dental enamel forms a protective coating over the tooth. This coating consists mainly of calcium, phosphate, and other ions in a hydroxyapatite-like structure. The enamel contains 2 to 5 percent carbonate; this carbonate content makes the enamel susceptible to acid dissolution. See, *Featherstone*, id. at 6.

The interaction of three factors is believed to result in dental caries: a susceptible tooth surface; the proper microflora; and a suitable substrate for the microflora. Although several acidogenic micro-organisms that are present in the mouth can initiate carious lesions, *Streptococcus mutans* is believed to be the primary pathogen. See, *The Merck Manual*, supra.

It is known that foods containing fermentable carbohydrates can promote dental caries. Tooth decay begins when the *Streptococcus mutans*, that reside principally in the plaque that adheres to a tooth surface, metabolizes the fermentable carbohydrates that are consumed by the host. During the metabolism of the fermentable carbohydrates by the bacteria, lactic acid and other organic acids are secreted as a by-product. These acids reduce the pH of the surrounding plaque/tooth environment.

When the pH of the plaque/tooth environment drops below a critical level of 5.5 to 5.7, hydroxyapatite (calcium phosphate hydroxide, $Ca_{10}(PO_4)_6(OH)_2$), the key component of tooth enamel, begins to dissolve. This critical pH can change depending on the concentration of the key ions. Typically, the dissolution begins below the tooth's porous surface.

With repeated acid attacks, caused by the further metabolism of fermentable carbohydrates by the bacteria, subsurface lesions expand. The body's natural remineralization mechanism, however, at this point, can still reverse the decay process. But, if the lesions expand to the point that the enamel surface breaks, a cavity is formed and the process is no longer reversible.

The natural remineralization process involves, in part, the flow of saliva over the plaque. The saliva can raise the pH of the environment. Additionally, calcium and phosphate ions in the saliva precipitate out to replace the hydroxyapatite that was dissolved by the organic acids created during the metabolism of the fermentable carbohydrates.

However, typically, this remineralization process only occurs at significant levels when the pH is above the critical level (5.5 to 5.7). Therefore, if the saliva does not sufficiently raise the pH, significant remineralization will not occur. But, the remineralization process may be enhanced by fluoride in the oral cavity that speeds up new crystal growth and makes a flurorapatite-like material that is precipitated on the surface of the crystals inside the caries lesion. See, *Featherstone, id.* at 7.

A number of salts have been reported in certain experiments to counteract demineralization. One of the difficulties is providing a viable vehicle for delivering the salts. Still further, a number of safety issues are raised by some of the salts. Furthermore, sensory problems with respect to some of the salts prevent these salts from being taken on a regular basis by a patient to provide prophylactic benefits. Another problem is that these calcium salts can add significant cost to a product.

Calcium containing compositions are used in chewing gum. Specifically, a number of current chewing gum products use calcium carbonate as a base filler. Additionally, calcium carbonate is used in chewing gum formulas to modify chewing texture. Calcium carbonate is very water insoluble. Accordingly, even though calcium

carbonate is added to a chewing gum base, it does not release in sufficient levels into the mouth of chewer in order to enhance the remineralization of tooth enamel.

Although it is known to add acids to chewing gum to provide a tart flavor, calcium carbonate is typically not used in such situations. In this regard, talc is normally used as the base filler since acids are neutralized by calcium carbonate.

U.S. Patent No. 5,378,171 discloses a sugar chewing gum with dental health benefits that includes calcium glycerophosphate.

SUMMARY OF THE INVENTION

The present invention provides a composition and method for the remineralization of enamel. Pursuant to the present invention, sugar free chewing gum is provided that includes a therapeutically effective amount of calcium and a food grade acid. It has been found that the food grade acids when added to a calcium containing base will convert insoluble calcium carbonate to its more soluble salt. This will allow the calcium to be released into the salvia in the mouth of the chewer. This provides calcium that can be used to enhance remineralization and/or reduce demineralization of tooth enamel.

To this end, the present invention provides a sugar free chewing gum comprising an insoluble portion, a water soluble portion, a flavor, calcium carbonate, and a food grade acid.

In an embodiment of the present invention, the food grade acid is chosen from the group consisting of: lactic acid; phosphoric acid; citric acid; malic acid; ascorbic acid; formic acid; fumaric acid; succinic acid; and tartaric acid.

In an embodiment of the present invention, the calcium carbonate comprises approximately 0.1% to about 20% by weight of the chewing gum.

In an embodiment of the present invention, the chewing gum includes at least one additional oral health ingredient.

In an embodiment of the present invention, the food grade acid comprises approximately 0.4% to about 5% by weight of the chewing gum.

In an embodiment of the present invention, a sugar free chewing gum is provided that includes a water soluble portion, a water insoluble portion, a sufficient amount of an insoluble calcium salt containing composition to produce a calcium ion concentration in

the mouth of the chewer of at least 100 ppm, and a food grade acid.

In an embodiment, the food grade acid is chosen from the group consisting of: lactic acid; phosphoric acid; citric acid; malic acid; ascorbic acid; formic acid; fumaric acid; succinic acid; and tartaric acid.

In an embodiment, the calcium carbonate containing composition comprises approximately 0.1% to about 20% by weight of the chewing gum.

In an embodiment, the food grade acid comprises approximately 0.4% to about 5% by weight of the chewing gum.

In a still further embodiment of the present invention, a method for enhancing the remineralization of teeth is provided the method comprises the steps of: providing a sugarless chewing gum including a water soluble portion, a water insoluble portion, calcium carbonate, and a food grade acid; and chewing the sugarless chewing gum.

In an embodiment, two pieces of chewing gum are chewed at a time.

In an embodiment, the chewing gum is chewed at least twice a day.

In an embodiment, the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 100 ppm.

In an embodiment, the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 300 ppm.

In an embodiment, the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 500 ppm.

In an embodiment, the calcium ion concentration is maintained in the saliva for at least 2 minutes.

An advantage of the present invention is to provide a method for preventing or reducing the risk of dental caries.

Another advantage of the present invention is to provide a method for the remineralization of enamel.

A still further advantage of the present invention is to treat dental caries.

Additionally, an advantage of the present invention is to provide a chewing gum that can be used to improve dental health.

Further, an advantage of the present invention is to provide a chewing gum that does not have the sensory drawbacks of other sources of calcium.

Moreover, an advantage of the present invention is to provide an easy and enjoyable way to improve dental health.

A further advantage of the present invention is that it provides a chewing gum having dental benefits and a reduced cost.

Still further, an advantage of the present invention is to provide a composition and method for delivering a therapeutic agent over a prolonged period of time to the oral region.

Additional features and advantages of the present invention are described, and will be apparent from, the detailed description of the presently preferred embodiments and the drawings.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates graphically saliva extraction data, setting forth calcium released over time, for Examples 6-8 discussed *infra*.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention provides methods and compositions for the remineralization of tooth enamel. Thus, the present invention provides methods and compositions for preventing and/or treating dental caries. Pursuant to the present invention, a chewing gum is provided that includes a therapeutically effective amount of calcium and a food grade acid; the chewing gum of the present invention can improve dental health when chewed.

It has specifically been found that the addition of food grade acids to gum bases containing calcium carbonate will convert insoluble calcium carbonate to its more soluble salt when gum is chewed. Thus, when the gum will enhance remineralization and/or reduce demineralization in the mouth of the chewer.

A variety of food grade acids can be used. Such acids include lactic acid, phosphoric acid, citric acid, malic acid, ascorbic acid, formic acid, fumaric acid, succinic acid, and tartaric acid and mixtures thereof. For example, citric acid converts calcium carbonate to calcium citrate; lactic acid converts calcium carbonate to calcium lactate;

and phosphoric acid converts calcium carbonate to calcium phosphate. These acids have been found to maintain a pH level of approximately 5 to 7 in the gum as the acids are converted to their respective salts. Because the food grade acid, e.g., citric acid, when added to a sugarless chewing gum containing calcium carbonate converts the insoluble calcium carbonate to its more soluble salt, it can enhance remineralization.

Food acids are typically much less expensive than the corresponding calcium salts. Calcium carbonate is very inexpensive and typically is present in chewing gum products. As a result, the chewing gums of the present invention are less expensive to manufacture than gums formulated with the equivalent calcium salt.

Preferably, the chewing gum will comprise approximately 0.1% to about 20% by weight calcium carbonate preferably approximately 1% to about 15% by weight, and most preferably approximately 3% to about 12% by weight calcium carbonate. Sufficient calcium carbonate should be present in the chewing gum to create a calcium concentration in the saliva of at least 100 ppm, preferably at least 300 ppm, and most preferably at least 500 ppm for at least one minute, preferably more than two minutes, and most preferably for four minutes upon chewing the gum.

This is accomplished by incorporating at least 4mg, preferably at least 5mg, and most preferably 8mg of food grade acid, e.g., citric acid, per piece of chewing gum. Preferably, the food grade acid, e.g., citric acid is mixed into the chewing gum mass, but may also be pre-blended with calcium carbonate prior to mixing.

As noted above, other food grade acids aside from citric acid may be utilized in the present invention including phosphoric, lactic, malic, tartaric, formic, fumaric, succinic, and ascorbic acids. It has been found that these acids are more effective than others in generating calcium ions in saliva during chewing. Although the inventors do not want to be bound to any specific theory, they believe the reason for this is due to the dissociation constants of the acids and to the solubility of the resultant calcium salt.

The chewing gum composition may be any sugarless chewing gum formula. Such formulas typically contain a major amount of a sugar alcohol bulking agent, a substantial portion of gum base, minor amounts of syrups, softeners, flavors, color and high intensity sweeteners. Low calorie gums which contain reduced levels of sugar alcohols and increased levels of base and/or low calorie or calorie-free bulking agents are

also anticipated. The product may be formed into tabs, sticks, chunks or coated pellets. A piece size of approximately 1 to about 5 grams is preferred.

Chewing gum generally consists of a water insoluble gum base, a water soluble portion, and flavors. The water soluble portion dissipates with a portion of the flavor over a period of time during chewing. The gum base portion is retained in the mouth throughout the chew.

The insoluble gum base generally comprises elastomers, resins, fats and oils, softeners, and inorganic fillers. The gum base may or may not include wax. The insoluble gum base can constitute approximately 5 to about 95 percent, by weight, of the chewing gum, more commonly, the gum base comprises 10 to about 50 percent of the gum, and in some preferred embodiments, 20 to about 35 percent, by weight, of the chewing gum.

In an embodiment, the chewing gum base of the present invention contains about 20 to about 60 weight percent synthetic elastomer, 0 to about 30 weight percent natural elastomer, about 5 to about 55 weight percent elastomer plasticizer, about 4 to about 35 weight percent filler, about 5 to about 35 weight percent softener, and optional minor amounts (about one percent or less) of miscellaneous ingredients such as colorants, antioxidants, etc.

Synthetic elastomers may include, but are not limited to, polyisobutylene with GPC weight average molecular weight of about 10,000 to about 95,000, isobutylene-isoprene copolymer (butyl elastomer), styrene-butadiene copolymers having styrene-butadiene ratios of about 1:3 to about 3:1, polyvinyl acetate having GPC weight average molecular weight of about 2,000 to about 90,000, polyisoprene, polyethylene, vinyl acetate-vinyl laurate copolymer having vinyl laurate content of about 5 to about 50 percent by weight of the copolymer, and combinations thereof.

Preferred ranges are, for polyisobutylene, 50,000 to 80,000 GPC weight average molecular weight, for styrene-butadiene, 1:1 to 1:3 bound styrene-butadiene, for polyvinyl acetate, 10,000 to 65,000 GPC weight average molecular weight with the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetate-vinyl laurate, vinyl laurate content of 10-45 percent.

Natural elastomers may include natural rubber such as smoked or liquid latex and

guayule as well as natural gums such as jelutong, lechi caspi, perillo, sorva, massaranduba balata, massaranduba chocolate, nispero, rosindinha, chicle, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, sorva and massaranduba balata.

Elastomer plasticizers may include, but are not limited to, natural rosin esters such as glycerol esters of partially hydrogenated rosin, glycerol esters polymerized rosin, glycerol esters of partially dimerized rosin, glycerol esters of rosin, pentaerythritol esters of partially hydrogenated rosin, methyl and partially hydrogenated methyl esters of rosin, pentaerythritol esters of rosin, synthetics such as terpene resins derived from alpha-pinene, beta-pinene, and/or d-limonene; and any suitable combinations of the foregoing. The preferred elastomer plasticizers will also vary depending on the specific application, and on the type of elastomer which is used.

Fillers/texturizers may include magnesium and calcium carbonate, ground limestone, silicate types such as magnesium and aluminum silicate, clay, alumina, talc, titanium oxide, mono-, di- and tri-calcium phosphate, cellulose polymers, such as wood, and combinations thereof. In the present invention, calcium carbonate is the preferred filler but other fillers may be used if calcium carbonate is added separately.

Softeners/emulsifiers may include tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids (e.g. stearic, palmitic, oleic and linoleic acids), and combinations thereof.

Colorants and whiteners may include FD&C-type dyes and lakes, fruit and vegetable extracts, titanium dioxide, and combinations thereof.

The base may or may not include wax. An example of a wax-free gum base is disclosed in U.S. Patent No. 5,286,500, the disclosure of which is incorporated herein by reference.

In addition to a water insoluble gum base portion, a typical chewing gum composition includes a water soluble bulk portion and one or more flavoring agents. The water soluble portion can include bulk sweeteners, high intensity sweeteners, flavoring

agents, softeners, emulsifiers, colors, acidulants, fillers, antioxidants, and other components that provide desired attributes.

Softeners are added to the chewing gum in order to optimize the chewability and mouth feel of the gum. The softeners, which are also known as plasticizers and plasticizing agents, generally constitute between approximately 0.5 to about 15% by weight of the chewing gum. The softeners may include glycerin, lecithin, and combinations thereof. Aqueous sweetener solutions such as those containing sorbitol, hydrogenated starch hydrolysates, corn syrup and combinations thereof, may also be used as softeners and binding agents in chewing gum.

Bulk sweeteners typically constitute 5 to about 95% by weight of the chewing gum, more typically, 20 to 80% by weight, and more commonly, 30 to 60% by weight of the gum.

Sugarless sweeteners include, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, and the like, alone or in combination.

High intensity artificial sweeteners can also be used, alone or in combination with the above. Preferred sweeteners include, but are not limited to sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, coacervation, and fiber extension may be used to achieve the desired release characteristics.

Usage level of the artificial sweetener will vary greatly and will depend on such factors as potency of the sweetener, rate of release, desired sweetness of the product, level and type of flavor used and cost considerations. Thus, the active level of artificial sweetener may vary from 0.02 to about 8%. When carriers used for encapsulation are included, the usage level of the encapsulated sweetener will be proportionately higher.

Combinations of sugar and/or sugarless sweeteners may be used in chewing gum. Additionally, the softener may also provide additional sweetness such as with aqueous

sugar or alditol solutions.

If a low calorie gum is desired, a low caloric bulking agent can be used. Example of low caloric bulking agents include: polydextrose; Raftilose, Raftilin; Fructooligosaccharides (NutraFlora); Palatinose oligosaccharide; Guar Gum Hydrolysate (Sun Fiber); or indigestible dextrin (Fibersol). However, other low calorie bulking agents can be used.

A variety of flavoring agents can be used. The flavor can be used in amounts of approximately 0.1 to about 15 weight percent of the gum, and preferably, 0.2 to 5%. Flavoring agents may include essential oils, synthetic flavors or mixtures thereof including, but not limited to, oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oil, oil of wintergreen, anise and the like. Artificial flavoring agents and components may also be used. Natural and artificial flavoring agents may be combined in any sensorially acceptable fashion.

Additional oral health ingredients may be added including but not limited to pH control agents (such as urea and buffers), other inorganic components for tartar or caries control (phosphates, fluorides), and anti-plaque/anti-gingivitis agents (including chlorhexidene, CPC, triclosan). Any additional ingredients must be safe and effective and not react undesirably with calcium carbonate or the food grade acid of choice.

By way of example and not limitation, examples of the present invention are as follows:

EXAMPLES

	1	2	3	4	5
Gum Base (17.00% $CaCO_3$)	30.40%	29.00%	30.00%	30.00%	35.00%
Sorbitol	38.05	39.20	24.00	41.00	40.50
Xylitol	15.60	15.07	14.00	0.50	0.50
Mannitol	4.00	2.00	4.00	-	7.00
Maltitol	-	-	11.10	7.00	-
Glycerol	3.00	5.00	-	-	10.2
Sorbitol Solution (70% solids)	-	-	3.00	10.00	-

	Calcium Carbonate	5.00	5.00	6.00	-	-
	Citric Acid	0.70	-	0.50	-	-
	Lactic Acid	-	1.00	-	-	-
	Phosphoric Acid	-	-	1.00	-	1.50
5	Calcium Carbonate (77%)\Citric Acid Pre-blend (23%)	-	-	-	7.80	-
	Encapsulated Acesulsame K	0.47	0.67	0.90	-	0.55
10	Magnasweet	0.40	0.70	-	0.30	0.40
	Urea	-	-	3.00	-	2.50
	Aspartame	0.12	0.10	-	0.20	0.30
	Color	0.06	0.06	-	0.20	0.05
	Flavor	2.20	2.20	2.50	3.00	1.50
15						
	TOTAL	100.00%	100.00%	100.00%	100.00%	100.00%
	Form	2g tab	3g stick	3g stick	1.5g pellet (center)	4g chunk
	Flavor	Fruit	Bubble Gum	Cinnamon	Fruit	Peppermint

20

It should be noted that Example 4 is a pre-blended mixture of calcium carbonate and citric acid. Any food grade acid may be substituted in any desired amount. Example 5 does not use additional calcium carbonate in the formula. Rather, the acid can react with the calcium carbonate that exists in the base.

25 Testing was conducted to determine the effects of selected food grade acids with calcium carbonate upon saliva stimulated by chewing sugarfree gum. Three subjects participated in the study. Subjects chewed the gums of Examples 6, 7, and 8. Each sample was evaluated over a timed twenty minute period with saliva collected (without swallowing) at specified intervals. Prior to the twenty minute period, subjects were 30 required to chew a measured gum base sample (0.60g +/- 0.05g) for two minutes to establish the calcium content of saliva at baseline. Collected saliva samples were

weighted, vortexed, diluted to volume, and analyzed by atomic adsorption (AA) to determine calcium concentration which was adjusted for each subject's baseline value. Gum cuds were retained to complete mass balance calculations.

Three gum formulas were prepared according to Examples 6, 7, and 8 below. The batches received extended mix times to ensure an even distribution of the food grade acid and calcium carbonate additive. Pieces were cut to 2.00g-2.10g and aged for two weeks prior to testing. Samples were analytically tested to confirm correct formulation and acid neutralization.

EXAMPLES

Ingredients	Comparative 6	Inventive 7	Inventive 8
Gum Base (20.00% $CaCO_3$)	30.40%	30.40%	30.40%
Sorbitol	41.75	38.05	38.05
Xylitol	15.60	15.60	15.60
Mannitol	4.00	4.00	4.00
Glycerol	3.00	3.00	3.00
Calcium Carbonate	2.00	5.00	5.00
Citric Acid	-	0.70	-
Lactic Acid (88.00% solution)	-	-	0.70
Encapsulated Acesulsame K	0.67	0.67	0.67
Magnasweet	0.20	0.20	0.20
Aspartame	0.12	0.12	0.12
Color	0.06	0.06	0.06
Flavor (Bubble Gum)	2.20	2.20	2.20
TOTAL	100.00%	100.00%	100.00%

Both inventive composition Examples (7 and 8), released higher levels of calcium during the chew than the control (6). Figure 1 illustrates, graphically, those results.

The test results for inventive examples 7 and 8 are consistent with data expected based on salt solubility. Calcium carbonate becomes more soluble in an acidic solution. Results are consistent with expectations based on the strength of the acid employed and the solubility of the corresponding salt generated. Moreover, more calcium can be released during the chew to enhance beneficial dental properties with a higher solubility of calcium salts.

Based on these results it was concluded that the addition of food grade acids to products containing calcium carbonate does increase the amount of calcium released into

the saliva. Also, it must be noted that by employing a stronger acid, a more soluble calcium salt can be generated.

Trained sensory technicians conducted a descriptive panel with a control and two experimental gums each having differing amounts of citric acid. The gums tested were formulated as set forth below:

	EXAMPLES		
INGREDIENTS	**EXAMPLE 9 CONTROL**	**EXAMPLE 10 CITRIC ACID ADDED 1.00%**	**EXAMPLE 11 CITRIC ACID ADDED 1.50%**
Gum Base (20.00% $CaCO_3$)	30.40%	30.40%	30.40%
Sorbitol	41.75	39.75	39.25
Xylitol	15.60	15.60	15.60
Mannitol	4.00	4.00	4.00
Glycerol	3.00	3.00	3.00
Calcium Carbonate ($CaCO_3$)	2.00	3.00	3.00
Citric Acid	-	1.00	1.50
Encapsulated Acesulsame K	0.67	0.67	0.67
Magnasweet	0.20	0.20	0.20
Aspartame	0.12	0.12	0.12
Color	0.06	0.06	0.06
Flavor (Bubble Gum)	2.20	2.20	2.20
TOTAL	100.00%	100.00%	100.00%

The panel concluded that the two experimental formulas containing the citric acid were acceptable in terms of bubble gum, however they did not match the same flavor profile of the control. Each of the experimental samples exhibited a sour, acidic character in the initial chew. The experimental gums started to become similar to the control after

thirty seconds with the sour/tart notes disappearing. Additionally, the two experimental samples exhibited a thin, weak, bubble. The sample containing the 1.00% citric acid was considered to be closest to the control.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

WE CLAIM:

1. A sugar free chewing gum comprising:

a water insoluble gum base portion;

a water soluble portion;

a flavor;

calcium carbonate; and

a food grade acid.

2. The sugar free chewing gum of Claim 1 wherein the food grade acid is chosen from the group consisting of: lactic acid; phosphoric acid; citric acid; malic acid; ascorbic acid; formic acid; fumaric acid; succinic acid; and tartaric acid.

3. The sugar free chewing gum of Claim 1 wherein the calcium carbonate comprises approximately 0.1% to about 20% by weight of the chewing gum.

4. The sugar free chewing gum of Claim 1 including at least one additional oral health ingredient.

5. The sugar free chewing gum of Claim 1 wherein the food grade acid comprises approximately 0.4% to about 5% by weight of the chewing gum.

6. The sugar free chewing gum of Claim 1 wherein the food grade acid is citric acid.

7. A sugar free chewing gum comprising:

a water soluble portion;

a water insoluble gum base portion;

a sufficient amount of calcium carbonate to produce a calcium ion concentration in the mouth of the chewer of at least 100 ppm; and

a food grade acid.

8. The sugar free chewing gum of Claim 7 wherein the food grade acid is chosen from the group consisting of: lactic acid; phosphoric acid; citric acid; malic acid; ascorbic acid; formic acid; fumaric acid; succinic acid; and tartaric acid.

9. The sugar free chewing gum of Claim 7 wherein the calcium carbonate comprises approximately 0.1% to about 20% by weight of the chewing gum.

10. The sugar free chewing gum of Claim 7 including at least one additional oral health ingredient.

11. The sugar free chewing gum of Claim 7 wherein the food grade acid comprises approximately 0.4% to about 5% by weight of the chewing gum.

12. The sugar free chewing gum of Claim 7 wherein the food grade acid is citric acid.

13. The sugar free chewing gum of Claim 7 wherein the calcium carbonate produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 300 ppm.

14. A method for enhancing the remineralization of teeth comprising the steps of:

providing a sugarless chewing gum including a water soluble portion, a water insoluble portion, calcium carbonate, and a food grade acid; and

chewing the sugarless chewing gum.

15. The method of Claim 14 wherein two pieces of chewing gum are chewed at a time.

16. The method of Claim 14 wherein the chewing gum is chewed at least twice a day.

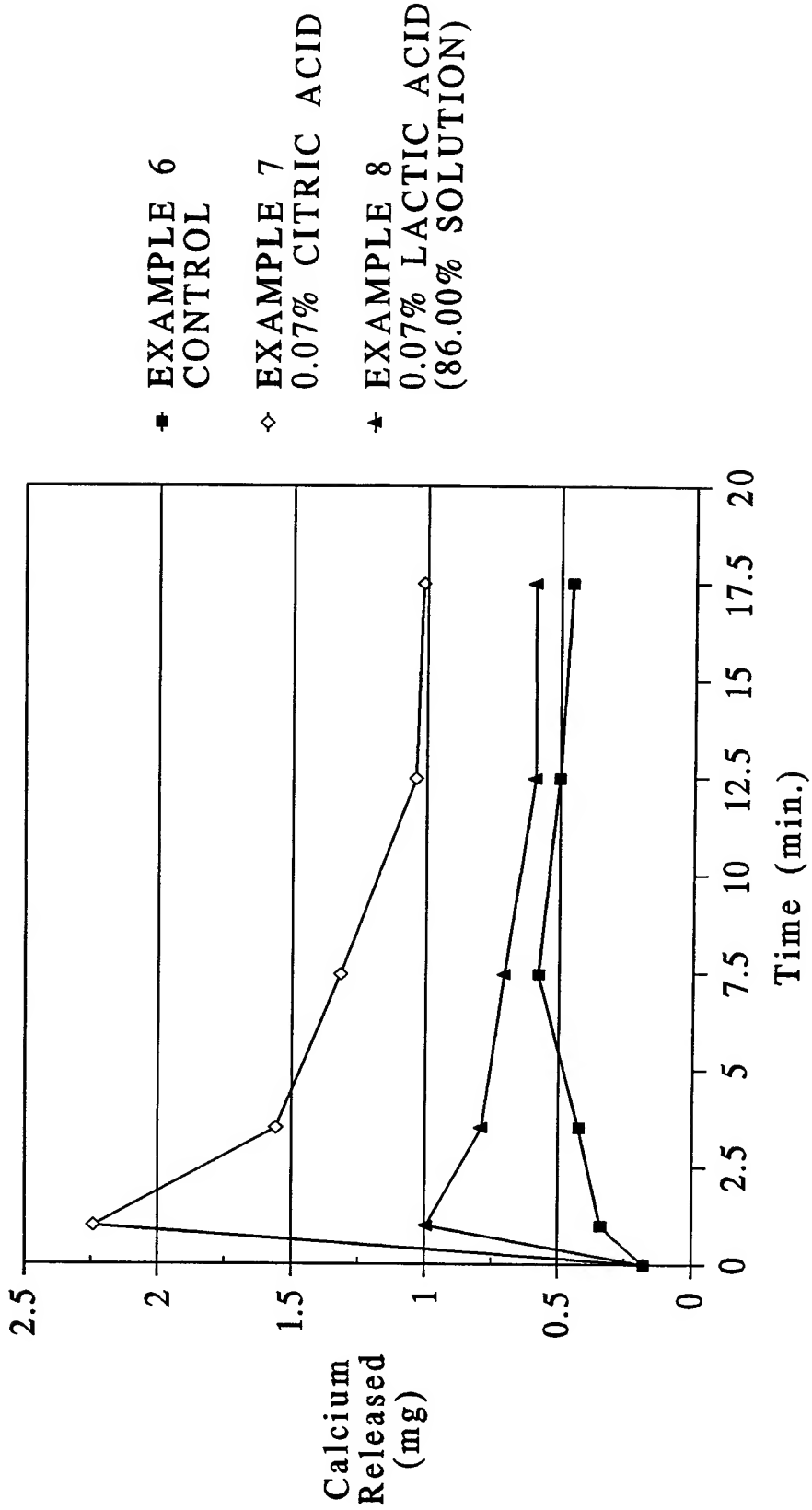
17. The method of Claim 14 wherein the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 100 ppm.

18. The method of Claim 14 wherein the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 300 ppm.

19. The method of Claim 14 wherein the chewing gum produces a calcium ion concentration in the saliva of the mouth of the chewer of at least 500 ppm.

20. The method of Claim 17 wherein the calcium ion concentration is maintained in the saliva for at least 2 minutes.

FIG.1


EXAMPLE 6
CONTROL
EXAMPLE 7
0.07% CITRIC ACID
EXAMPLE 8
0.07% LACTIC ACID
(86.00% SOLUTION)
Calcium Released (mg)
2.5
2
1.5
1
0.5
0
0
2.5
5
7.5
10
12.5
15
17.5
20
Time (min.)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07410

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61K 9/68; A23 G 3/30
US CL :424/48; 426/3,5

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/48; 426/3,5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 4,208,431 A (FRIELLO ET AL) 17 June 1980 (17-06-80), see entire document.	1-6, 14 ---------- 7-13,15-20
X ---- Y	US 4,238,475 A (WITZEL ET AL) 09 December 1980 (09-12-80), see entire document.	1-6, 14 ---------- 7-13,15-20
X ---- Y	US 4,975,270 A (KEHOE) 04 December 1990 (04-12-90), see entire document.	1-4, 6,14 ---------- 5, 7-13, 15-20

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 MAY 2000	Date of mailing of the international search report 30 MAY 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ARTHUR L. CORBIN DEBORAH THOMAS PARALEGAL SPECIALIST Telephone No. (703) 308-3850

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07410

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 5,882,702 A (ABDEL-MALIK ET AL) 16 March 1999 (16-03-99), see entire document.	1, 3-5, 14 ---------- 2, 6-13, 15-20